DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-378/S-026 & S-029

Serono, Inc.
Attention: Pamela Williamson Joyce
Vice President, Regulatory Affairs
One Technology Place
Rockland, MA 02370

Dear Ms. Williamson Joyce:

Please refer to your supplemental new drug applications dated August 23, 2002, and January 10, 2003, received August 26, 2002, and January 13, 2003, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gonal-f® (follitropin alfa for injection).

These "Changes Being Effected" supplemental new drug applications provide for editorial changes to the label (S-026) including updating the company logo and an editorial change to the blister pack label for the administration syringe (S-029).

We completed our review of these applications and they are approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling dated August 23, 2002 and January 10, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavyweight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-378/S-026, & S-029." Approval of these submissions by FDA is not required before the labeling is used.

In addition, as required by 21 CFR 314.550, submit three copies of all promotional materials including promotional labeling and advertisements that you intend to use within 120 days following approval of this product. Submit all proposed materials in draft or mock up form, not final print. Send one copy to this Division/the Division of Reproductive and Urologic Drug Products, HFD-180 and two copies of both the promotional materials and the proposed package insert directly to:

Division of Drug Marketing, Advertising
And Communications, HFD-42
Food and Drug Admnistration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Archana Reddy, M.P.H., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products (HFD-580)
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames
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